K010824

JUN - 5 2001

8.0 510(K) SUMMARY

Submitters name:

Science Incorporated
7760 France Avenue South, Suite 1060
Bloomington, MN 55435
(952) 835-1333
(952) 835-1716 (fax)
Contact person: Lynn S. Weist, Regulatory Affairs & Quality Assurance Director

Device name:	Proprietary name:	To be determined (in this document, the device is referred to as the **Science Incorporated Personal Infusor Local Pain Management Procedural Kit** or **Express**)
	Common name:	Elastomeric pump
	Classification name:	Infusion pump
Predicate device:	**PainBuster™ Infusion System** manufactured by I-Flow Corporation(K982946, K980558)	

Device description:

The **Science Incorporated Personal Infusor Local Pain Management Procedural Kit** consists of a **Personal Infusor** provided in a kit with medical device components including a catheter set, catheter introducer, 60 mL syringe, dressings and accessories. Each of the additional medical device components is purchased in finished form and is packaged with the **Personal Infusor** in the **Personal Infusor Local Pain Management Procedural Kit.**

The **Personal Infusors** provided in the **Personal Infusor Local Pain Management Procedural Kit** will be offered in three volume / flow rate configurations.

Personal Infusor Configurations

Volume	Delivery Time	Flow Rate
50 mL	96 hours (labeled maximum)	0.5 mL/hr
100 mL	96 hours (labeled maximum)	1.0 mL/hr
100 mL	50 hours	2.0 mL/hr

Intended use:

The **Science Incorporated Personal Infusor Local Pain Management Kit** is intended to provide continuous infusion of physician-prescribed local anesthetic medications directly into the intraoperative site of a patient for management of postoperative pain. Medication is delivered percutaneously, through the infusor's administration line, which is attached to a catheter.

The **Personal Infusor** is portable and is suitable for use by ambulatory patients.

The **Personal Infusor** is intended for single use only.

The **Personal Infusor** is not intended for rapid infusion, intravenous or intra-arterial drug infusion, for the delivery of blood, blood products, lipids, or fat emulsions, or for use by patients with a history of allergic reactions to anesthetics.

Technological characteristics

Both the **Personal Infusor** and the predicate device pumps are elastomeric pumps whose fluid reservoir includes an elastomeric membrane component. The strain energy of the elastomeric membrane provides energy in the form of pressure to drive the pump. Medication is delivered through an attached administration line which includes a fixed rate flow control tubing element that prevents run away infusion rates, an in-line vent / filter and On / Off clamp. Both devices provide continuous, fixed rate, infusions for local pain management

Performance data:

Flow performance tests demonstrate that the **Personal Infusor** meets operational specifications for flow rate accuracy and delivery time of ± 15 % of the labeled flow rate. The operational specifications are consistent with those stated for the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2001

Ms. Lynn S. Weist
Regulatory Affairs & Quality Assurance Director
Science, Incorporated
7760 France Avenue South
Bloomington, Minnesota 55435-5803

Re: K010824
Trade/Device Name: Personal Infusor Local Pain Management Procedural Kit
Regulation Number: 880.5725
Regulatory Class: II
Product Code: MEB
Dated: March 16, 2001
Received: March 19, 2001

Dear Ms. Weist:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010824

Science Incorporated
7760 France Avenue South, Suite 1060
Bloomington, MN 55435-5803

510(k) Number:_____

Device Name: Science Incorporated Personal Infusor Local Pain Management Procedural Kit

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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